

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

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THIS DOCUMENT RELATES TO  
ALL CLASS ACTIONS

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) MDL No. 1456  
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) CIVIL ACTION: 01-CV-12257-PBS  
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) Judge Patti B. Saris  
)

) Chief Magistrate Judge Marianne B. Bowler  
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) **[FILED UNDER SEAL]**  
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**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO  
DEFENDANTS' MOTION TO STRIKE THE HARTMAN DECLARATION**

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## I. INTRODUCTION

Defendants' motion seeking to strike the Declaration of Dr. Raymond Hartman amounts to little more than an effort to gain additional pages to re-hash arguments in opposition to class certification. In stark contrast to the Plaintiffs' motions filed this day to strike the three defense declarations of Mssrs. Young, Gaier and Navarro – motions grounded on fundamental flaws of expertise, or of non-disclosure, or of revealed disabling bias – Defendants' motion to strike the Hartman declaration amounts to little more than a disagreement with the results of an expert they implicitly acknowledge is imminently qualified to render opinion in pharmaceutical pricing matters. The motion should be denied.

## II. THE STANDARD FOR EVALUATING EXPERT TESTIMONY SUPPORTING CLASS CERTIFICATION: THE BASIS OF THE OPINION MUST NOT BE SO FLAWED AS TO BE INADMISSABLE AS A MATTER OF LAW

It is not uncommon for plaintiffs to put forward expert evidence at the class certification stage to demonstrate that methodologies exist to allow the case to be determined on a class basis. But, contrary to Defendants' argument, the Court need not and should not conduct a full *Daubert* analysis at the class certification stage.<sup>1</sup> This is because the merits of an expert report are scrutinized differently on a class motion than they are at summary judgment or trial.<sup>2</sup>

“In assessing whether to certify a class, the Court’s inquiry is limited to whether or not the proposed methods are so insubstantial as to amount to no method at all.” *In re Potash Antitrust Litig.*, 159 F.R.D. 682, 697 (D. Minn. 1995). In *Visa Check*, the Second Circuit

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<sup>1</sup> It appears that the First Circuit has never addressed this precise issue. Accordingly, Plaintiffs rely on cases from other jurisdictions and particularly on recent and convincing Second Circuit jurisprudence.

<sup>2</sup> See, e.g., *Caridad v. Metro-North Commuter R.R.*, 191 F.3d 283, 292 (2d Cir. 1999) (expert “dueling is not relevant to the certification determination” even though it may “prove fatal at the merits stage”); *In re Sumitomo Copper Litig.*, 182 F.R.D. 85, 91 (S.D.N.Y. 1998) (expert’s deficiency “is a matter to be ascertained by trial and not for a determination as to the appropriateness of class certification”); *In re Industrial Diamonds Antitrust Litig.*, 167 F.R.D. 374, 384 (S.D.N.Y. 1996) (“[w]e need not consider [defendants’ expert’s criticisms of methodology employed by plaintiffs’ expert] in detail, as it is for the jury to evaluate this conflicting evidence and to determine what weight to give to the experts’ conclusions”); *In re Disposable Contact Lens Antitrust Litig.*, 170 F.R.D. 524, 531 (M.D. Fla. 1996) (certifying class where plaintiffs “demonstrated at least a ‘colorable method’ of proving impact at trial, even where defense expert “disagrees with the methodology and conclusions propounded”); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 262 (D. Mass. 2004) (“Court may not at this preliminary stage ‘weigh conflicting expert evidence or engage in ‘statistical dueling’ of experts.”) (quoting *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 135 (2d. Cir. 2001), *cert. denied*, 122 S. Ct. 2382 (2002)).

explained that the district court's function at the class certification stage is merely to determine whether the proposed methodology is "fatally flawed." 280 F.3d at 135. The court noted that a full *Daubert* analysis should occur later in litigation, typically in connection with a motion for summary judgment, motions *in limine* or trial. *Id.* at 132 n.4. In discussing *Visa Check*, Judge Scheindlin recently observed:

In the context of expert reports, ... *VISA Check* teaches that a district court "may not weigh conflicting expert evidence or engage in 'statistical dueling' of experts." ... Instead, the *sole* job of a district court in assessing expert evidence on a class certification motion is to "ensure that the basis of the [plaintiff's] expert opinion is not so flawed that it would be inadmissible as a matter of law."

*In re Initial Pub. Offering Sec. Litig.*, 2004 U.S. Dist. Lexis 20497, at \*\*83-84 (S.D.N.Y. Oct. 13, 2004) (footnotes omitted).<sup>3</sup>

The principal reason for the limited review of expert testimony at the class certification stage is that a limited review avoids the inappropriate consideration of the merits of plaintiffs' claims.<sup>4</sup> Moreover, at the class certification stage, it would be unreasonable to expect plaintiffs to have been able to conduct a full analysis of the claims. In complex litigation such as this, an expert's full analysis will require extensive discovery that has not yet been completed. *See, e.g., In re Visa Check/MasterMoney Antitrust Litig.*, 192 F.R.D. 68, 76 (E.D.N.Y. 2000) (noting that *Daubert* inquiry is relaxed because class certification is neither a trial nor summary judgment

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<sup>3</sup> *See also In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 698 (S.D. Fla. 2004) (at class certification stage, plaintiffs need only come forward with "plausible statistical or economic methodologies ..."); *Nichols v. Smithkline Beecham Corp.*, 2003 U.S. Dist. Lexis 2049, at \*\*10-11 (E.D. Pa. Jan. 29, 2003) (expert opinion need not satisfy *Daubert* to be admissible for class certification purposes); *Anderson v. Boeing*, 222 F.R.D. 521, 526-27 (N.D. Okla. 2004) (same). That defendants have chosen to attack Dr. Hartman's affidavit through a motion to strike rather than in response to class certification does not alter the standards to be applied at this stage of the litigation. *See, e.g., Anderson*, 222 F.R.D. at 526-27 (applying limited scrutiny to expert testimony in response to motion to strike at class certification stage).

<sup>4</sup> *Anderson*, F.R.D. at 526; *Thomas & Thomas Rodmakers, Inc. v. Newport Adhesives & Composites, Inc.*, 209 F.R.D. 159, 162-63 (C.D. Cal. 2002) (lower *Daubert* standard should be used at class certification stage); *see also Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 297-98 (1st Cir. 2000) (in conducting a rigorous analysis of the prerequisites established by Rule 23, the court does not determine whether plaintiffs will prevail on the merits) (citing *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 178 (1974)).

exercise). Thus, the full gate-keeping function of *Daubert* – which was “designed to shield the fact-finder at trial from flawed evidence” – should not be applied at this time. *Id.*<sup>5</sup>

### III. HARTMAN’S OPINION IS WELL-GROUNDED IN ECONOMIC THEORY AND THE FACTS OF THIS CASE AND IS ADMISSIBLE FOR PURPOSES OF CONSIDERING CLASS CERTIFICATION

Applying the above standards, courts regularly accept the base methodology employed by Dr. Hartman here. Dr. Hartman’s proposed methodology will ascertain whether and to what extent the class was injured by Defendants’ fraudulent pricing:

- Using industry price compendia and other available data sources, Dr. Hartman will ascertain the spreads between AWP and ASP for drugs unaffected by the scheme and fraud. These spreads will be used as “yardsticks” for the reasonable expectations of the market of drug purchasers as to the spread between AWP and ASP.
- Using the same types of public information, as well as data derived from a detailed analysis of Defendants’ invoice and accounting data, Dr. Hartman will ascertain the spreads between AWP and ASP for the drugs subject to this litigation.
- Dr. Hartman proposes comparing the spreads of drugs in this litigation against the “yardstick” spreads for the drugs unaffected by the fraudulent scheme. The comparison will yield relevant information for purposes of determining whether and to what extent the affected drugs’ prices were inflated by the fraudulent scheme.
- If the analysis demonstrates that prices were inflated by the fraudulent scheme, Dr. Hartman then proposes to use the “yardstick” spreads as a comparison to determine the spread that would have been used for the affected drugs but-for the wrongful scheme.
- Using mathematical and algebraic formulae, Dr. Hartman can make this analysis for each affected drug and, applying actual sales figures and prices, determine the overall class-wide injury and damage for each drug.

Dr. Hartman’s methodology starts and ends with unexceptional and widely-used economic tools, including data collection, econometrics, algebra and mathematics.<sup>6</sup> These tools

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<sup>5</sup> Defendants’ principal authorities are not persuasive because the courts in those decisions employed a full *Daubert* review without analyzing whether doing so was appropriate at the class certification stage. *See* Defs. Br. at 5-6 (citing *Bell v. Ascendant Solutions, Inc.*, 2004 U.S. Dist. Lexis 12321 (N.D. Tex. July 1, 2004); *Yapp v. Union Pac. R.R. Co.*, 301 F. Supp. 2d 1030 (E.D. Mo. 2004); *McNamara v. Bre-X Minerals Ltd.*, 2002 U.S. Dist. Lexis 27473 (E.D. Tex. Sept. 30, 2002); *Corley v. Entergy Corp.*, 220 F.R.D. 478 (E.D. Tex. 2004); *Sanneman v. Chrysler Corp.*, 191 F.R.D. 441 (E.D. Pa. 2000)). Defendants’ suggestion that Judge Young’s limited review at the class certification stage in *Relafen* is “inconsistent” with *Tardiff v. Knox County*, 365 F.3d 1, 4-5 (1st Cir. 2004), *see* Defs. Br. at 5 n.4, is totally incorrect, as the *Tardiff* opinion did not even consider expert testimony.

<sup>6</sup> *See, e.g.*, Hartman Reply Declaration (“HRD”) at ¶ 14(i) pp. 12-13, ¶¶ 31, 32 p. 38 describing “standard quantitative methods” he uses; and Section F pp. 42-48 describing “standard econometric techniques” used to show relationship between AWP and reimbursement. Hartman Decl. ¶¶ 20-27.

are widely used by experts in cases alleging improper price inflation, and courts regularly deem them reliable for expert analysis. *See, e.g., Ohio ex rel. v. Louis Trauth Dairy, Inc.*, 925 F. Supp. 1247, 1252 (S.D. Ohio 1996) (econometric and statistical analyses generally considered reliable disciplines; allowing expert to testify on injury and damages in pricing case based on these methodologies); *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 566 (11th Cir. 1998) (compilations of data using simple arithmetic, algebra and other economic analyses are methodologies that are well established as reliable).

The heart of Dr. Hartman's methodology is to apply these tools to create a "yardstick" measure. Like the underlying tools, the yardstick methodology to determine whether and by how much prices were inflated is well accepted by courts. In *Terazosin*, the court held that Dr. Hartman's proposed methodology for showing class-wide injury and damages in an antitrust suit was sufficient to support class certification. The court recognized that the yardstick method of economic analysis was "widely accepted" and had been "used in numerous other antitrust class actions." 220 F.R.D. at 699. Similarly, in *In re Cardizem CD Antitrust Litig.*, the court found admissible an expert report using the yardstick approach to measure the impact of defendant's wrongdoing and assess class-wide damages. The court noted that the expert's methodology found support in government and academic studies and scientific articles, and that data was available to conduct the methodology. 200 F.R.D. 326, 349 (E.D. Mich. 2001).<sup>7</sup>

As these cases demonstrate, Dr. Hartman's yardstick methodology, derived from standard tools of economics, is – at a minimum – reliable for class certification purposes. No further inquiry is needed.

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<sup>7</sup> *See also* *Midwestern Mach. v. Northwest Airlines*, 211 F.R.D. 562, 566 (D. Minn. 2001) (accepting under *Daubert* a benchmarking approach similar to "yardstick" to determine affect of improper actions on pricing); *In re Potash Antitrust Litig.*, 159 F.R.D. 682 (D. Minn. 1995) (methodology of comparing conspiracy pricing and profits with those in similar industry not subject to conspiracy was acceptable for class certification); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 522 (S.D.N.Y. 1996) (noting that yardstick methodology is acceptable approach to ascertain damages); *In re Commercial Tissue Prods. Antitrust Litig.*, 183 F.R.D. 589, 595 (N.D. Fla. 1998) (explaining that, "even if there is considerable individual variety in pricing because of individual price negotiations, class plaintiffs may succeed in proving classwide impact by showing that the minimum baseline for beginning negotiations, or the range of prices which resulted from negotiation, was artificially raised (or slowed in its descent)").



#### IV. HARTMAN'S OPINION IS ADMISSIBLE EVEN UNDER THE STRICTER *DAUBERT* STANDARD

Whether the Court evaluates Dr. Hartman's report on a limited basis to determine whether it is "fatally flawed" or undertakes a complete *Daubert* analysis, it will find that Dr. Hartman's report should not be stricken and is admissible for purposes of evaluating class certification. Under *Daubert*, two considerations guide the Court in deciding whether to admit expert evidence. First, the expert must be shown to be **qualified** by "knowledge, skill, experience, training or education" in his or her area of expertise. Fed. R. Evid. 702. Second, the evidence must be both **relevant** to the case and **reliable**. See *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993); *Smith v. General Electric Co.*, 2004 U.S. Dist. Lexis 7011, at \*8 (D. Mass. Apr. 23, 2004); Fed. R. Evid. 702. Dr. Hartman's opinions satisfy each of these inquiries: he is eminently qualified to issue the report, his report is relevant to the case and his methodology is sound.

##### A. Defendants Do Not Challenge Dr. Hartman's *Qualifications* Or The *Relevance* Of His Testimony And Effectively Concede That Both Of These Factors Are Satisfied

Defendants do not attack Dr. Hartman's qualifications to testify. Their only quibble is to pin on him the label of the "go-to" litigation economist for plaintiffs' counsel." Defs. Br. at 3. But Dr. Hartman has consulted for defendants and government entities, as well as private plaintiffs. Hartman Decl. at ¶ 4.<sup>8</sup> That he has substantial experience consulting with plaintiffs' counsel in no way disqualifies him from testifying here. His exceptional credentials as an economist, a professor and a consultant fully qualify him as an expert in this matter.

Defendants effectively concede the relevance of Dr. Hartman's testimony. Indeed, courts regularly consider testimony relating to determining class-wide injury and measuring class-wide damages in ruling on class certification. See, e.g., *Terazosin*, 220 F.R.D. at 699; *Cardizem CD*, 200 F.R.D. at 348-50.

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<sup>8</sup> "Hartman Decl." refers to the declaration that Dr. Hartman submitted in support of Plaintiffs' motion.

**B. Dr. Hartman's Opinion Is Reliable**

Dr. Hartman's opinions are also reliable under the *Daubert* test. The purpose of expert testimony is to assist the trier of fact in determining contested issues. *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998) (court should consider whether expert's opinion likely would assist trier of fact in understanding or determining issue in case). *Daubert* identified a number of factors that district courts "may" consider in determining whether scientific evidence is valid: (i) whether the method has been tested; (ii) whether it has been subject to peer review; (iii) whether it has been evaluated in light of a potential rate of error; and (iv) whether it is consistent with the generally accepted method for gathering the relevant evidence. 509 U.S. at 593-94. These factors are "meant to be helpful, not definitive" and not exclusive. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 151 (1999). Indeed, the *Daubert* factors may not apply in every situation, and an expert's testimony may be acceptable even if it does not satisfy each of the factors. *Id.*

The district court has considerable latitude in deciding how to test an expert's reliability and in determining which, if any, of the factors outlined in *Daubert* are helpful to the analysis. *Kumho Tire*, 526 U.S. at 150-52. The inquiry is "a flexible one," and the focus must be "solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 594-95; *see also U.S. v. Lopez-Lopez*, 282 F.3d 1, 14 (1st Cir. 2002) (test for reliability is flexible one and factors listed in *Daubert* do not necessarily or exclusively apply to all experts or every case; law grants district court broad latitude in how to determine reliability). Thus, *Daubert* does **not** require the party proffering the expert to prove that the expert's assessment is correct. "As long as an expert's scientific testimony rests upon 'good grounds, based on what is known'... it should be tested by the adversary process – competing expert testimony and active cross-examination – rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." *Ruiz-Troche*, 161 F.3d at 85. Defendants may disagree with Dr. Hartman's approach or argue that his methodology will not work. But

their disagreement is not for the Court to decide on a *Daubert* motion and, most certainly, not on a *Daubert* motion at the class certification stage. *See, e.g., Terazosin*, 220 F.R.D. at 699 (defendants' objections to underlying assumptions on which calculations are based do not defeat class certification because plaintiffs at the class stage need only demonstrate that methodologies are available); *Cardizem*, 200 F.R.D. at 351 (not necessary for plaintiffs to show that experts' methods will work with certainty; rather, their burden is to present court with a likely method to determine class damages); *Rondout Valley Central School Dist. v. Coneco Corp.*, 321 F. Supp. 2d 469, 478 (N.D.N.Y. 2004) (disagreements about factors used to calculate damages are better left for cross-examination than exclusion).

Contrary to Defendants' assertion, the *Daubert* factors support admissibility of Dr. Hartman's opinions. The testing, peer review and general acceptance factors<sup>9</sup> are satisfied by the fact that Dr. Hartman's yardstick methodology, based on common tools such as econometrics, data collection, algebraic formulas and mathematics, have been widely used in scientific analysis of the penetration of generic drugs and in a variety of legal cases involving pricing overcharges. *See* Hartman Decl. at 10-11, n.24-26; *Cardizem*, 200 F.R.D. at 348 (accepting expert methodology based on economic methods that have been widely accepted); *Terazosin*, 220 F.R.D. at 699 (same); *Rmed International Inc. v. Sloan's Supermarkets, Inc.*, No. 94 Civ. 5587, 2000 WL 310352 at \*10 (S.D.N.Y. 2000) (accepting expert testimony relying on accepted principles articulated in relevant economic literature); *Rondout*, 321 F. Supp. 2d at 478 (expert methodology accepted where it resembles standard economic valuation processes).<sup>10</sup>

Furthermore, and as noted above, several courts have endorsed benchmarking approaches to market pricing cases.<sup>11</sup> *See* *Midwestern Mach.*, 211 F.R.D. at 566; *NASDAQ*, 169 F.R.D. at

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<sup>9</sup> One of the four factors – whether the opinion has been evaluated in light of a potential rate of error – does not apply here.

<sup>10</sup> Even Dr. White's utilizes a similar methodology in his own calculations. *See* Declaration of Raymond S. Hartman in Rebuttal to Dr. Halbert L. White (the "White Rebuttal") at ¶ 16.

<sup>11</sup> A listing of such cases is also attached as Appendix A to Plaintiffs' Reply Memorandum in Support of Class Certification.

522; *Commercial Tissue*, 183 F.R.D. at 595. In short, the Court should join the *Terazosin* court in recognizing that the yardstick method of economic analysis is “widely accepted” and has been used in numerous market pricing class actions. *See* 220 F.R.D. at 699.

**V. DEFENDANTS’ ATTACKS ON DR. HARTMAN’S METHODOLOGY ARE FACTUALLY AND LEGALLY INCORRECT**

**A. It Is Wholly Appropriate For Dr. Hartman To Adapt Standard Econometric Analysis To The Specific Circumstances Of This Case**

Defendants attack Dr. Hartman for purportedly creating a methodology specifically for this case. Defs. Br. at 3. But almost every case must rise or fall on its own merits, and it would be unrealistic to expect publication or peer review of the precise formulae and approaches to be used in any given case. *See Harcross*, 158 F.3d at 566 n.25 (proper inquiry is not whether exact methodologies have been tested where there are likely to have been few or no cases with substantially similar facts; rather inquiry is whether techniques used to develop methodology are reliable); *cf. Kumho Tire*, 526 U.S. at 151 (would not be surprising if expert witness’s claim had not been subject to peer review; implying that that would not defeat admissibility). That Dr. Hartman has created a model that takes into account the unique qualities and nuances of this case, while using tools and techniques that have wide acceptance in the economic and legal communities, supports a finding of sufficient reliability for class certification purposes. *See Kumho Tire*, 526 U.S. at 150 (gatekeeping inquiry must be tied to facts of particular case).

**B. Dr. Hartman’s Methodology Does Not Assume Liability, And Variations In Individual Negotiations Do Not Render The Methodology Unreliable**

**1. Hartman’s methodology does not assume what it seeks to prove**

Defendants’ exclaim that Dr. Hartman’s methodology is “hardwired to find class-wide causation, injury and liability, because it assumes away the very question it purports to address.” Defs. Br. at 9. Yet, the only matters that Dr. Hartman assumes are the truth of the complaint’s allegations of AWP inflation. Hartman Decl. ¶ 8. Defendants and their expert, Halbert White, refer to this assumption as a “tautology,” but they are mistaken. As a threshold matter, it is

commonplace for experts to assume the truth of a complaint's allegations when rendering opinions at the class certification stage. White Rebuttal at ¶ 7. Indeed, White *admits* that he believes that it is standard practice to assume the truth of plaintiffs' allegations. White Tr. at 52 ("I understand that in this process of certifying a class, the allegations are assumed to be true and there is the need to determine whether or not impact and injury can be determined on the basis of common evidence."); *see also Terazosin*, 220 F.R.D. at 699 (defendants' objections to underlying assumptions on which calculations are based do not defeat class certification because plaintiffs at the class stage need only demonstrate that methodologies are available). Not surprisingly, then, Dr. Hartman has followed convention and assumed the truth of Plaintiffs' allegations.

What Dr. Hartman has *not* assumed is that class members have been adversely impacted by the AWP inflation. Instead, Dr. Hartman *analyzed* whether that could be determined by employing well-accepted economic methodology. *See, e.g.*, Hartman Decl. at ¶ 7 ("I have been asked by counsel to evaluate the effects that Defendants' activities (if proven as alleged ...) had on the members of the respective Classes. I have been asked to analyze whether causation, injury and liability can be proven on a class-wide basis."); White Rebuttal at ¶ 15 ("I do not assume that all putative Class members were injured, nor was I asked by counsel to assume it. I was asked to assume that the AWP was inflated."). After conducting an extraordinary amount of research, including the review of hundreds-of-thousands of pages of documents (which included many, many studies) and a plethora of deposition transcripts, and applying his own very extensive experience in health care markets, Dr. Hartman has made a number of conclusions that are summarized as follows: (i) inflating AWP for a given drug inflates the AWP for all units of that drug because AWP is the industry-wide list price published in various industry price compendia and serves as a pricing standard or signal;<sup>12</sup> (ii) because the Class includes only

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<sup>12</sup> Dr. Hartman equates the reporting of WACs with AWPs "since the price compendia have a known formula by which they mark up WAC to obtain AWP by NDC." Hartman Decl. at 7 n.20. Thus, a manufacturer that reports inflated WACs is also inflating AWPs.

payors who made reimbursements based on AWP, the reimbursement rates paid by all or substantially all members of the class will be artificially inflated; and (iii) as a result, class members were injured and overcharged. Hartman Decl. at ¶ 10; HRD at ¶ 14 pp. 9-13.

To be sure, this part of Dr. Hartman's analysis may appear simple, but that is only because of the industry's ubiquitous use of AWP as a reimbursement standard. As Dr. Hartman explains:

Put most simply, since Defendants are alleged to have artificially inflated their reported AWP's, and since the Classes are defined as including those payors whose reimbursement rates are "based upon the use of AWP as a pricing standard," **how is it possible that Class members are not impacted by the alleged violations?** The quantum of impact remains to be determined, but the fact of impact certainly does not. ... [T]he economic impacts involved common injury and damages that are measurable by standard economic formulaic methodologies. [White Rebuttal at ¶ 9.]

Although the analysis is straight-forward, it most certainly does not follow that Dr. Hartman has merely assumed that injury has occurred.<sup>13</sup>

Further, Dr. Hartman's model carefully has accounted for the alleged "variations" in individual negotiations. First, his model takes into account differences in discounts as a result of such "negotiations."<sup>14</sup> Second, as he explains, the tight cluster of discounts at 14% to 18% off AWP is an economic indicator that there were no meaningful "negotiations" due to an absence of information about true prices.<sup>15</sup>

## 2. **The subjective expectations of individual class members and other variations in the net prices paid by class members need not be exhaustively surveyed**

Defendants spend much of their brief arguing that Dr. Hartman's proposal to ascertain the reasonable expectations of the market for a spread between AWP and ASP cannot be valid unless he ascertains the "subjective" expectations of individual class members and otherwise

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<sup>13</sup> For a more detailed response to White's conclusion that Dr. Hartman relies upon a tautology, see ¶¶ 6-13 of the White Rebuttal, which is incorporated herein by this reference.

<sup>14</sup> HRD Section IV, pp. 48-60 (addressing each variable). *See also* HRD p. 59 and Figure 1.

<sup>15</sup> HRD ¶ 41, pp. 51-53; ¶¶ 48-56, pp. 62-67.

digs into all of the individual negotiations and variables that preceded the final net price that each class member paid for AWPIDs. Defs. Br. at 7-12, 15-17. But such an inquiry is unnecessary and unsupported by persuasive case law.

“Expectations” can be determined formulaically and objectively, using economic data and analysis. Specifically, Dr. Hartman’s approach is to establish a yardstick (“expectations”) through either “using actual data from those manufacturers and their drugs known to be unaffected by the AWP scheme” and/or using industry-wide survey information (again, actual data) regarding the relationship between AWP and ASP for drugs not affected by the unlawful scheme. Hartman Decl. at 18 and Appendix C. As Dr. Hartman explained in his initial declaration:

Given the lack of pricing transparency in this industry ... and given the widespread use of AWP as a pricing reference point, market expectations about the manufacturers’ ASPs and thus providers’ and other intermediaries AACs have been determined by a drug’s AWP. While some end payers have understood that the AWP is greater than the manufacturer’s average sale price (ASP), they must still look to a drug’s AWP as the only publicly available signal for the manufacturers’ ASP of the drug (hence, the providers’ AAC of the drug). That is, they have expected that AWP is larger than ASP by *a reasonably predictable amount*.... Absent information on the actual ASP, end payers depend upon AWP to decide the competitive value of a drug, relative to alternative therapies. [Hartman Decl. at ¶ 10(b) (footnote omitted).]

Having continued his intensive study of these matters since producing his original opinions, Dr. Hartman now reinforces these conclusions:

The injury and overcharge induced by the fraudulent AWP scheme was positively related to the extent to which the AWP was artificially inflated above the transaction prices for which that AWP was taken as a signal. Specifically, contrary to Defendants’ experts assertions (as discussed below), the AWP is interpreted by the market as a signal for other relevant prices: the WAC; the manufacturer net sales price (the ASP); and the actual acquisition cost borne by the relevant providers (the AAC). The greater the divergence between the AWP and the ASP or AAC, the less reliable was the AWP as a signal to the payors negotiating reimbursement rates. ... It is precisely this divergence, AWP – ASP, which increases the “Spread” defined in my September 3,

2004 Declaration. ... Hence, class-wide injury and damages are positively related to measures of the Spread. [HRD at ¶ 14(d) (footnotes omitted).]

Because of the lack of transparency, and because AWP served as the benchmark for all of the class members' contracts, market participants could not and did not act strategically to eliminate or dissipate the injury. AWP "was the *only price signal publicly available to all payors* ... for the manufacturers' ASP of the drug and/or the providers' AAC of the drug." Consequently, all class members negotiated from that same signal, even if some payors "paid no attention to the relationship between AWP and the underlying transaction prices" and even if some "informed payors understood that the AWP is greater than the manufacturer's" ASP. HRD at ¶ 14(f)(i).<sup>16</sup> Thus, Dr. Hartman's "formulaic methodology allows for a **distribution** of expectations and information among Class members concerning" the relationship between AWP and actual prices "and explicitly accounts for the effect of those expectations (and other factors) on the reimbursement rates negotiated." HRD at ¶ 16(i).<sup>17</sup>

Dr. Hartman likens the impact of AWP inflation to what can happen in other markets that utilize list prices:

For purposes of understanding this market and the allegations made in this Complaint, the AWP is no different than list prices used in many industries and markets, and the impact and injury caused by a fraud to artificially inflate the AWP are no different than those of a fraud to inflate other list prices. For example, consider market pricing for new automobiles. One expert knowledgeable of the pharmaceutical industry, already quoted by me and Defendants' experts, characterizes the AWP as "a 'sticker price' or 'list price,' as those terms are used in the automobile industry." ... In the automobile market, consumers know, or should know, that the manufacturer average sale price (ASP) and the dealer acquisition cost (AAC) are less than the sticker price (AWP). Some consumers may be better informed than others; some may negotiate more aggressively than others. However, the

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<sup>16</sup> Dr. Hartman explains in detail why as a matter of economic analysis, the "expectations" of the market can be objectively measured based on the behavior of market participants, and he has done so. HRD at ¶¶ 48-56 at pp. 62-67.

<sup>17</sup> For a more thorough exposition of why it is unnecessary to consider all possible variations and expectations between and among the individual Class members, see ¶¶ 37-61 of the HRD, which are incorporated herein by this reference.



final price negotiated by each consumer **starts with that sticker price**. The negotiated final price is informed by some notion of margins earned by dealers and manufacturers and some information regarding ASP and AAC. The final prices negotiated will vary across consumers. However, all prices will reference that sticker price and will be distributed around an average discount “off” that sticker price, and the final prices negotiated by consumers will be statistically related to sticker prices over time and across automobiles. **Should sticker prices be artificially and fraudulently inflated, all consumers negotiating prices will have been impacted and injured, unless they fully understood all the details of the fraud and could fully negotiate with the dealer to eliminate the fraudulent overcharges.** The number of consumers so positioned is *de minimus*. The number of payors that were so positioned (with regard to all claims) relative to the fraudulent AWP scheme is *de minimus*. [HRD at ¶ 16(e) (footnote omitted).]

The salient point of Dr. Hartman’s analysis is as follows: When the price signal is inflated, the end result of negotiations is an inflated payment – regardless of the net magnitude of any discounts from the benchmark – because the entire pricing curve has been shifted *upward*. Consequently, this case resembles securities fraud and antitrust cases, where illegal behavior leads to a market-wide inflation of prices, regardless of what end-payers expect to or are willing to pay. Indeed, courts have endorsed this very methodology.<sup>18</sup> For instance, in *In re Commercial Tissue Prods.*, 183 F.R.D. at 595, the court recognized that, notwithstanding individual price negotiations among many industry players, if such negotiations start from a minimum baseline range of prices, common impact results. In doing so, the court rejected the exact same arguments advanced by Defendants here regarding the need to consider individualized expectations and negotiations, and found that other courts had drawn the same conclusion:

The heart of defendants’ argument is that individual questions of fact and law predominate over the general questions of law and fact because the price paid by each distributor was determined through an elaborate system of individualized negotiations, contracts and rebates. To determine any classwide impact, argue the defendants, you must first prove the impact, if any, on each of

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<sup>18</sup> A table of cases accepting this methodology is contained in Appendix A to Plaintiffs’ Reply Memorandum in Support of Motion for Class Certification.

the class members. Because pricing in the industry is allegedly so individualized, the plaintiffs will be unable to show any consistent classwide relationship between the acts of the defendants and the prices paid by class members. Or at the very least, argue the defendants, proving such impact will require infinite mini-trials concerning the price actually paid by each class member.

While defendants' argument is attractive at first blush, closer analysis reveals its flaws. First, ***many cases have held that even if there is considerable individual variety in pricing because of individual price negotiations, class plaintiffs may succeed in proving classwide impact by showing that the minimum baseline for beginning negotiations, or the range of prices which resulted from negotiation, was artificially raised (or slowed in its descent) by the collusive actions of the defendants.*** See, e.g., *In re Catfish Litigation*, 826 F. Supp. 1019 (N.D. Miss. 1993); *In re Infant Formula Antitrust Litigation*, 1992 WL 503465, at \*5 (Jan. 13, 1992) ("Contentions of infinite diversity of product, marketing practices, and pricing have been made in numerous cases and rejected. Courts have consistently found the conspiracy issue the overriding, predominant question"); *In re Domestic Air Transp.*, 137 F.R.D. 677, 689 (N.D. Ga.1991) (inflated fares resulted in artificial "base" price which became benchmark for discounted or negotiated fares); *Hedges Enterprises, Inc. v. Continental Group, Inc.*, 81 F.R.D. 461, 475 (E.D. Pa.1979) (despite negotiated or discounted prices, artificial minimum became "base" price). In the instant case, as in the Corrugated Carton, NASDAQ, Plywood, Glassine and Small Bags cases, the plaintiffs allege that any individual price negotiations for commercial tissue products began from price lists or guidelines which plaintiffs allege were artificially and unlawfully inflated by the conspiracy. Thus defendants' argument that diversity of pricing destroys predominance is unavailing. [Id. (emphasis added).]

The court in *Terazosin* echoed a similar conclusion:

While Defendants complain that Dr. Hartman's methodologies are too imprecise for class certification, and further object to many of the underlying assumptions upon which his calculations are based, such contentions cannot defeat class certification. ... [F]or class certification purposes, plaintiffs need not supply a precise damage formula and the Court need not decide which approach is best-suited to the particularities of this case. "It is sufficient to note at this stage that there are methodologies available, and that Rule 23(c)(1) and (d) allow ample flexibility" to deal with the individual damages issues that may develop. [220 F.R.D. at 699 (quoting *NASDAQ*, 169 F.R.D. at 522).]<sup>19</sup>

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<sup>19</sup> At this stage, the Court need not determine "what approach is best suited to the particularities of th[e] case" for determining damages. *NASDAQ*, 169 F.R.D. at 522. "It is sufficient to note at this stage [class certification] that there are methodologies available, and that Rule 23(c)(1) and (d) allow ample flexibility" to deal with individual damage questions. *Id.*; *Cardizen*, 200 F.R.D. at 349-50.

Defendants cite no authority for their proposition that Plaintiffs must prove individual class members' subjective expectations. Moreover, the fact that there may be individual differences among class members that the expert's methodology does not address is irrelevant for class certification purposes. See *Midwestern Machinery*, 211 F.R.D. at 567-68 (argument that each class member will have to be evaluated individually may impact weight that court will give to expert report on class certification but does not impact admissibility).

Although couched as attacks on methodology, the gravamen of Defendants' argument is that they disagree with Dr. Hartman's conclusions. For instance, they may argue that AWP is not a benchmark price, that prices would have remained the same if another benchmark were used, and that "bundles" of PBM services serve to dissipate the impact of the fraud. But such contentions – even if true (and they are not) – do not render Dr. Hartman's conclusions inadmissible, for it is the province of jury to decide which expert is correct.<sup>20</sup> *Smith v. General Elec. Co.*, 2004 U.S. Dist. Lexis 7011, at \*15 (fact finder determines whether the expert's assessment of the situation is correct); *Polanio v. Bayer Corp.*, 122 F. Supp. 2d 63, 66-67 (D. Mass. 2000) (doubts about the validity of the expert's ultimate conclusions will almost always be resolved by a fact finder); *Industrial Diamonds*, 167 F.R.D. at 384 ("it is for the jury to evaluate ... conflicting [expert] evidence and to determine what weight to give to the experts' conclusions"). Thus, Defendants are asking the Court to accept the conclusions of their experts over Plaintiffs' expert on a class certification motion. Granting this request would eviscerate the well-settled distinction between a merits and a class inquiry and overturn *Eisen* and *Mowbray*.

### **C. Dr. Hartman's Baseline ASP Calculation Is Reliable**

Defendants assail Dr. Hartman's baseline ASP calculation as unreliable and in conflict with Dr. Schondelmeyer's testimony because Hartman is including all classes of trade, including sales to hospitals. Defs. Br. at 12-15. But Defendants again are quibbling with ultimate

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<sup>20</sup> Further, Dr. Hartman's model will account for such factors and he will opine that bundling does not dissipate the fraud.

conclusions, which is improper at this stage. Moreover, with the benefit of discovery Dr. Hartman can decide at trial which classes should or should not be part of an ASP calculation – this is a pure merits determination.

**D. The White Declaration Does Not Trump Dr. Hartman’s Analysis**

Defendants rely heavily on the Declaration of Halbert L. White, Jr., Ph.D. (“White Declaration”) to opine that Dr. Hartman’s methodology is not “scientifically reliable” under *Daubert*. Professor White’s Declaration should not be considered by this Court for at least two reasons. First, White is not qualified to opine on whether a particular methodology is appropriate for class certification because he does not understand what is required for expert testimony at this stage, and other than reviewing (but not verifying) the opinions of Dr. Gaier, White has done absolutely no analysis of any documents or depositions in this case and therefore cannot opine on whether any of Dr. Hartman’s assumptions were reasonable. Second, White’s Declaration seeks to improperly usurp this Court’s gate-keeping function and, in any event, his opinions merely go to the weight accorded Dr. Hartman’s conclusions.

**1. White is not qualified to evaluate whether Dr. Hartman’s methodology is appropriate for class certification**

White has no experience with the class certification process and has *never* provided expert testimony in support of or in opposition to a motion for class certification. The testimony that he has provided in class actions has been related solely to liability or damages methodologies. White Tr. at 49; White Decl. at 8-9. White’s resulting misunderstanding of the purpose of Dr. Hartman’s analysis is evident when he criticizes Dr. Hartman for assuming the truth of Plaintiffs’ allegations. White Decl. at ¶ 10. As noted above, such assumptions are standard at this phase in the proceedings. Thus, White’s tautological predicate is but a sleight-of-hand crafted to confuse the Court and should be ignored.

This Court should disregard White's Declaration for an additional reason: White has done no independent or case-related research into Dr. Hartman's approach.<sup>21</sup> He did not review the AMCC, the Motion for Class Certification, or the expert declarations of any of Plaintiffs' or Defendants' experts other than the Gaier Declaration. White Tr. at 27-8.<sup>22</sup> Indeed, the *only* case-related documents in addition to the Gaier Declaration that White reviewed to prepare his Declaration were Dr. Hartman's Declaration and deposition testimony. White Tr. at 25-6.<sup>23</sup> Even the limited review of this material was fleeting, as White admitted to *skimming* Dr. Hartman's deposition transcript and selectively focusing on but a few sections. White Tr. at 26.

White's consideration of the Gaier Declaration was similarly superficial. He did not comprehensively review the exhibits thereto, White Tr. at 26, and only relied on the Gaier Declaration to credit Dr. Gaier for purportedly considering reasons that injury may not be class-wide. White Decl., ¶ 20.<sup>24</sup> Moreover, White repeatedly testified that the only significance that he placed on the Gaier Declaration was that Gaier's considerations should not be dismissed "out of hand." White Tr. at 69, 75.

Indeed, White's knowledge of the pharmaceutical industry generally and the allegations in this case specifically were so limited that he did not even draft his own Declaration and

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<sup>21</sup> White's failure to conduct an independent analysis is particularly troubling because of White's bias towards the pharmaceutical industry. Notably, White is the founder of BW Analytics, a firm whose sole purpose is "to improv[e] pharmaceutical brand performance," see <http://www.bwanalytics.com>, and to "use[] sophisticated analysis, technology, and world industry experience to help pharmaceutical firms improve marketing program profitability at all levels." See [http://www.bwanalytics.com/about/news/2002/03.01\\_launch.html](http://www.bwanalytics.com/about/news/2002/03.01_launch.html). Moreover, the Advisory Board of BW Analytics, appointed in October 1, 2003, includes Michael D. Casey, who worked at Defendant J&J as the Vice President of Sales of Ortho Pharmaceutical Corp. and was President of McNeil Pharmaceuticals. Professor White has also performed work for Ortho McNeil. See White Tr. at 4-5, 9-10 [HIGHLY CONFIDENTIAL].

<sup>22</sup> White's failure to do *any* investigation regarding the nature of the claims in the AMCC makes his Declaration even more unreliable because White testified that he only learned of the term AWP when his firm began work on this litigation. White Tr. at 11.

<sup>23</sup> White's failure to consider other documents is particularly ironic in light of his opinion that "[r]eliable application of scientific method requires consideration of relevant factors that might disprove Dr. Hartman's hypothesis." White Decl. at ¶ 20.

<sup>24</sup> None of the public documents that White reviewed related to the health care or pharmaceutical industry generally. White Tr. at 25-26.

instead relied on others on the Bates White “team” to prepare drafts for his review. White Tr. at 28. White further testified that he had only spent between twenty and thirty hours working on the Declaration. *Id.* at 19.

Accordingly, the Court should not consider White’s Declaration. Despite knowing relatively nothing about this case, White did nothing to educate himself about it before opining that Dr. Hartman, who provided an exhaustive report after reviewing hundreds of thousands of pages documents and multiple depositions, failed to conduct a proper class certification analysis. Furthermore, and even more troubling, White knows little about how the prescription drug market operates. As opined by Richard Frank, the Margaret T. Morris Professor of Health Economics at the Harvard University Medical School:

After reviewing relevant literature in health policy and health economics and considering the institutions of the pharmaceutical industry I conclude that Dr. White’s economic reasoning is devoid of content specific to the operation of pharmaceutical markets. His statement implies that there is a universal truth to how economic agents incorporate and act upon information. A basic understanding of how prescription drug markets operate at the very least raises important questions about the availability of information and the degree to which economic agents respond to such information. Dr. White seems to be so unfamiliar with pharmaceutical markets that his application of economic analysis to this sector is likely to produce results that are unreliable and incorrect. [Frank Decl. at ¶ 6.]

**2. Professor White’s declaration improperly usurps this Court’s gate-keeping function and, in any event, only goes to the weight of the evidence**

The Court should reject White’s declaration for the additional reason that White’s ultimate conclusion – that Dr. Hartman’s proposed damages methodology is “scientifically unreliable” – improperly seeks to usurp *the Court’s* role as a gatekeeper under *Daubert* or the more limited admissibility inquiry. Even so, it is important to highlight that White does not opine that Dr. Hartman’s *methodology* – multiple regression analysis – is unreliable. Instead, White concludes that Dr. Hartman’s use of that methodology is somehow faulty. But this conclusion goes to the weight – and not the admissibility – of the testimony. *See Smith v. General Elec. Co.*, 2004 U.S. Dist. Lexis 7011, at \*15 (“*Daubert* does not require that a party

who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process – competing expert testimony and active cross-examination – rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.”) (quoting *Ruiz-Troche*, 161 F.3d at 85) (internal citations omitted).

The Court's decision in *Polanio v. Bayer Corp.*, 122 F. Supp. 2d at 66-67, made this distinction particularly clear:

Expert testimony, of course, takes different forms. Least troubling to the judge is an opinion based on the interpretation of data that are not in dispute. An economist, for example, opining as to a plaintiff's lost future earnings, will ordinarily reach her conclusions using a generally accepted actuarial model based on the plaintiff's life expectancy, his past earnings history, and certain assumptions about the plaintiff's residual earning capacity and the prevailing discount rate. In this instance, it is not the expert's methodology that might be suspect, but the reasonableness of the assumptions that she has factored into her actuarial model. Doubts about the validity of her ultimate conclusions will almost always be resolved by a fact finder exposed to 'vigorous cross-examination . . . and careful instruction on the burden of proof.' (Citing *Daubert*, 509 U.S. at 596).

Similarly, in *Flebotte v. Dow Jones & Co.*, 2000 U.S. Dist. Lexis 19875 (D. Mass. Dec. 6, 2000) (Freedman, J.), the Court refused to strike the expert testimony of a statistician whose testimony was proffered in support of an age discrimination case, even though the Court found that the statistician had made some troubling and arguably unsupportable assumptions. As the Court explained, “statistical analyses need not include all measurable variables to be admissible” and

[w]hile the omissions of variables from a regression analysis may render the analysis less probative than it otherwise might be, it can hardly be said, absent some other infirmity, that an analysis which accounts for the major facts must be considered unacceptable as evidence. . . . Normally, failure to include variables will affect the analysis' probativeness, not its admissibility.

*Id.* at \*8 (quoting *Bazemore v. Friday*, 478 U.S. 385, 400 (1986)). Likewise, at most, White's Declaration opines that Dr. Hartman has failed to consider factors that Dr. Gaier allegedly

considered. These conclusions do not answer whether Dr. Hartman's methodology – the use of econometrics – is scientifically reliable. This provides yet another reason to reject White's "drive-by" opinions.<sup>25</sup>

## **VI. CONCLUSION**

For the reasons stated above, the Court should deny Defendants' motion to strike the Hartman Declaration.

DATED: December 17, 2004.

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<sup>25</sup> In the White Rebuttal at ¶¶ 17-21, Dr. Hartman catalogues in detail why White's conclusions are contradicted by the preponderance of econometric analysis, methods and theory. That discussion is incorporated herein by this reference.



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**CERTIFICATE OF SERVICE**

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing, **PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO STRIKE THE HARTMAN DECLARATION** to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 17, 2004, a copy to Verilaw Technologies for Posting and notification to all parties

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